



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,323	02/06/2002	Frank Himmelsbach	5/1252	2194

28505 7590 10/30/2002

BOEHRINGER INGELHEIM CORPORATION
900 RIDGEURY ROAD
P. O. BOX 368
RIDGEFIELD, CT 06877

[REDACTED] EXAMINER

TRUONG, TAMTHOM NGO

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER
1624

DATE MAILED: 10/30/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

}

Office Action Summary	Application No.	Applicant(s)
	09/914,323	HIMMELSBACH ET AL.
	Examiner Tamthom N. Truong	Art Unit 1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-20 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6+ | 6) <input type="checkbox"/> Other: _____. |

one filed on 8-24-01

DETAILED ACTION

Applicant's preliminary amendment of 2-5-02 has been entered. Claims 21 and 22 have been cancelled; leaving claims 1-20 pending for consideration.

Specification

1. The disclosure is objected to because of the following informalities: For the genus of formula (I), the specification lists A as "imino", but all disclosed species have A as "amino" (e.g., see definition of A on page 3, and species on page 105). Note, "imino" is C=N while "amino" is -N-.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

a. In claims 1-16, the definition of variable "A" includes an "imino" group.

However, the disclosed species do not have A as an "imino" group, but an "amino" group

Art Unit: 1624

instead. Thus, it is unclear what is intended for A. Clarification is solicited for variable

A.

- b. Claim 17 recites species with A as an “amino” group which are inconsistent with the genus of formula (I) described in the specification.
- c. Claims 18-20 are rejected as being dependent on claims 1-17.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

- 3. Claims 1, 5, 12, and 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by

Wissner et. al. (EP 787,722): For example, Wissner et. al. list compounds on lines 38 and 39 in claim 4, which are embraced by the claimed formula (I) with the following substituents:

- i. R_a is hydrogen; R_b is phenyl substituted with R₃ as a halogen;
- ii. X is nitrogen;
- iii. R_c and R_d are hydrogen atoms;
- iv. A is amino; B denotes a carbonyl;
- v. C represents 1,2-vinylene;
- vi. D denotes an alkylene; E stands for R₆-O-CO-; R₆ is hydrogen;

Art Unit: 1624

vii. F and G together represent hydrogen.

Said compounds inhibit EGF-R kinases, and can also treat abnormal cell growth such as tumors. Thus, at the time of the invention, one skilled in the art would have known how to make certain quinazoline compounds as claimed herein and use them to treat tumors as well as other related disorders.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

4. Claims 1, 5, 12, and 18-20 are rejected under 35 U.S.C. 102(a) as being anticipated by **Wissner et. al. (WO 98/43960)**. For example, the compound in Example 382 (page 172) is embraced by the instant formula I with the following substituents:

viii. R_a is hydrogen; R_b is phenyl substituted with R₃ as a halogen;

ix. X is a methine group substituted by a cyano group;

x. R_c and R_d are hydrogen atoms;

xi. A is amino; B denotes a carbonyl;

xii. C represents 1,2-vinylene;

xiii. D denotes an alkylene; E stands for R₆-O-CO-; R₆ is hydrogen;

xiv. F and G together represent hydrogen.

Art Unit: 1624

5. Claims 1, 5, 12, and 18-20 are rejected under 35 U.S.C. 102(a) as being anticipated by Wissner et. al. (WO 99/09016). For example, the compound in Example 4 (page 47) is embraced by the instant formula I with the following substituents:

- xv. R_a is hydrogen; R_b is phenyl substituted with R_3 as a halogen;
- xvi. X is nitrogen;
- xvii. R_c and R_d are hydrogen atoms;
- xviii. A is amino; B denotes a carbonyl;
- xix. C represents 1,2-vinylene;
- xx. D denotes an alkylene; E stands for $R_6-O-CO-$; R_6 is hydrogen;
- xxi. F and G together represent hydrogen.

The disclosed compounds in both WO patents can inhibit protein tyrosine kinase, and treat cancers. Thus, at the time of the invention, one skilled in the art would have known how to make certain quinoline and quinazoline compounds as claimed herein and use them to treat tumors as well as other related disorders.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

6. Claims 1, 5, 12, and 18-20 are rejected under 35 U.S.C. 102(e) as being anticipated by **Wissner et. al.** (US 6,002,008). For example, compound x in claim 20 (column 144, line 59) is embraced by the instant formula I with the following substituents:

- xxii. R_a is hydrogen; R_b is phenyl substituted with R₃ as a halogen;
- xxiii. X is a methine group substituted by a cyano group;
- xxiv. R_c and R_d are hydrogen atoms;
- xxv. A is amino; B denotes a carbonyl;
- xxvi. C represents 1,2-vinylene;
- xxvii. D denotes an alkylene; E stands for R₆-O-CO-; R₆ is hydrogen;
- xxviii. F and G together represent hydrogen.

The disclosed compounds can inhibit protein tyrosine kinase, and treat cancers. Thus, at the time of the invention, one skilled in the art would have known how to make certain quinoline compounds as claimed herein and use them to treat tumors as well as other related disorders.

Reference cited on PTO-892

The reference of **Frost et. al.** (US 6,384,051) is listed on PTO-892 because it appears to contain relevant subject matter. Because of its late filing date, it does not constitute a prior art. However, applicant is requested to review said reference as it could result in a potential interference.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 703-305-4485. The examiner can normally be reached on M-F (9:00-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


Mukund Shah
Supervisory Patent Examiner
Art Unit 1624



T. Truong

October 28, 2002


BRUCK KIFLE, PH.D.
PRIMARY EXAMINER